AUG 1 1 2005

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K052109

510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of this Pre-market Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official:	Daina L. Graham Vice President, Regulatory Affairs and Quality Assurance
E-mail:	Daina.Graham@sonosite.com
Telephone:	(425) 951-1275
Facsimile:	(425) 951-1201
Date prepared:	July 29, 2005

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite Hand-Carried Ultrasound System (C1 Series) *(subject to change)*

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the predicate or legally marketed device:

This 510(k) adds the clinical application "Small Organ (breast, thyroid, testicles, prostate)" to the indications for use of the transducer C60/5-2 5.0-2.0 MHz Curved Array on the SonoSite Hand-Carried Ultrasound System (C1 Series) (K010374 and K014116). No other change, including technological change was made to this system. A predicate device that has "Small Organ" as a clinical application or indication is Advanced Technology Laboratories HDI 5000 Ultrasound System (K011224).

4) Device Description:

The device referenced in this Submission is a highly portable, software-controlled, diagnostic ultrasound system with accessories. This Submission does not include any technological or feature changes from the previously cleared SonoSite devices or transducers.

By this Submission, the clinical application "Small Organ (breast, thyroid, testicles, prostate)" is being added to previously cleared indications for use to the following transducer:

System	Transducer	Transducer Type	Frequency Range
SonoSite Hand-Carried Ultrasound System	C60/5-2	Curved Array	5.0 – 2.0 MHz

FDA Recognized Consensus Standards that SonoSite Hand-Carried Ultrasound System (C1 Series) is designed to comply with, as applicable to its features, are listed below:

Applicable Standards

Reference No.	Title
AIUM	AIUM Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (1994)
ANSI/AAMI EC53	ECG Cables and Electrodes except for sections 4.4 and 4.5.9 (1995)
AAMI/ANSI/ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)
AAMI/ANSI/ISO 30993-4	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood (ISO 10993-4:1992)
AAMI/ANSI/ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:1999)
AAMI/ANSI/ISO 10993-10	Biological evaluation of medical devices - Part 10: tests for irritation and sensitization (ISO 10993-10:1995)
AAMI/ANSI/ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for systematic toxicity (ISO 10993-11:1993)

Reference No.	Title
AAMI/ANSI/ISO 10993-12	Biological evaluation of medical devices - Part 12: sample preparation and reference materials (ISO 10993-12:1996)
EN 980 A1	Graphical symbols for use in the labeling of medical devices (2003)
IEC 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988
IEC 60601-1/A1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A1:1991
IEC 60601-1/A2	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A2:1995 + corrigendum June 1995
IEC 60601-1-1	Medical electrical equipment. Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems – IEC 601-1-1:2000
IEC 60601-1-2	Medical electrical equipment – Part 1: General requirements for safety; 2. collateral standard: electromagnetic compatibility; requirements and tests - IEC 60601-1-2:200
IEC 60601-1-4	Medical electrical equipment – Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems - IEC 60601-1-4:1996 Amendment A1
IEC 60601-2-25	Medical Electrical Equipment–Part 2. Particular Requirements for Safety–Section 25. Specification for Electrocardiographs. (1999
IEC 60601-2-37	Medical Electrical Equipment – Part 2-37; Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (2001)
NEMA UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD 3-2004	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine

The following are other standards with which the SonoSite Hand-Carried Ultrasound System (C1 Series) complies, where applicable:

Miscellaneous Design Standards

Reference No.	Title
ASTM D5276-98	Standard Test Methods for Drop Test of Loaded Containers by Free Fall (1998)
ASTM D999-96	Standard Methods for Vibration Testing of Shipping Containers (1996)
CISPR 11	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment – Electromagnetic Disturbance Characteristics – Limits and Methods of Measurement (2003)
JIS-T-601-1	Japanese Standards for Medical Electrical Equipment
RTCA/DO160D	Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B (1997)
UL 60601-1	Underwriters Laboratories, Medical Electrical Equipment-Part 1: General Requirements for Safety (2003)
UL 94	Underwriters Laboratories, Inc., Tests for Flammability of Plastic Materials for Parts in Devices and Appliances, 5th Edition

5) Intended Use:

The intended uses of the SonoSite ultrasound system referenced herein remain unchanged from previously cleared indications, except for the addition of "Small Organ (breast, thyroid, testicles, prostate)" to the indications for use of the transducer C60/5-2 5.0-2.0 MHz Curved Array on the SonoSite Hand-Carried Ultrasound System (C1 Series) as a new intended use.

The intended uses of the SonoSite Hand-Carried Ultrasound System (C1 Series) as defined by FDA guidance documents, are:

Fetal - OB/GYN	Trans-rectal
Abdominal	Trans-vaginal
Intra-operative (Abdominal organs and vascular)	Musculo-skel. (Conventional)
Intra-operative (Neuro.)	Musculo-skel. (Superficial)
Pediatric	Cardiac Adult
Small Organ (breast, thyroid, testicles, prostate)	Cardiac Pediatric
Neonatal Cephalic	Peripheral vessel

6) Technological Characteristics:

There are no technological or feature changes in this Submission to any of the legally marketed ultrasound systems, transducers, or accessories identified in Section 3 of this Summary.

7) Testing:

The referenced SonoSite Hand-Carried Ultrasound System (C1 Series) has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, as well as thermal, electrical and mechanical safety, and has been found to conform to applicable medical device safety standards, as referenced in Section 4. Reports were previously included in the referenced predicate submissions. No additional clinical testing is required, as the added indication for use is not a novel indication as shown by the predicate devices in Section 3. The anatomical site is amenable to current transducer and post-processing ultrasound technology available with the SonoSite Hand-Carried Ultrasound System (C1 Series) and predicate devices. Additionally, the modes of operation that are indicated with this clinical application for the SonoSite Hand-Carried Ultrasound System (C1 Series) is consistent with those identified with the predicate devices.

8) Conclusion:

SonoSite believes that the testing and analysis described in Section 7 demonstrates that the SonoSite Hand-Carried Ultrasound System (C1 Series) (K010374 and K014116), incorporating the "Small Organ (breast, thyroid, testicles, prostate)" indication on the transducer C60/5-2 5.0-2.0 MHz Curved Array, are substantially equivalent with respect to safety and effectiveness to the predicate device identified in Section 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2005

SonoSite, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K052109
Trade Name: SonoSite Hand-Carried Ultrasound System (C-1 Series)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 2, 2005
Received: August 4, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite Hand-Carried Ultrasound System (C-1 Series), as described in your premarket notification:

Transducer Model Number

C60/5-2. 5.0-2.0 MHz Curved Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

David A. Lyerly

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Table 4.3- 1 Diagnostic Ultrasound Indications for Use Form - System

System:	SonoSite Hand-Carried Ultrasound System (C1 Series)
Transducer:	N/A
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1, 2
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Small Organ (breast, thyroid, testicles, **prostate**)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal	P	P	P			B+M; B+PWD	Note 1
	Trans-vaginal	P	P	P			B+M; B+PWD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
Cardiac	Cardiac Pediatric	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy cleared in K014116. Imaging guidance for peripheral nerve block procedures and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared in K033367.

Note 2: The clinical application Intra-operative (Neuro.) was previously cleared in K043452.

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)

Division of Reproductive, **Abdominal,** and Radiological Devices

510(k) Number K052109

Table 4.3- 2 Diagnostic Ultrasound Indications for Use Form - C60/5-2 Transducer

System:	SonoSite Hand-Carried Ultrasound System (C1 Series)
Transducer:	C60/5-2 5.0-2.0 MHz Curved Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD;	Note 1
	Abdominal	P	P	P			B+M; B+PWD;	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD;	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P			B+M; B+PWD;	Note 1
	Small Organ (breast, thyroid, testicles, prostate)	**N**	**N**	**N**			**B+M; B+PWD;**	**Note 1**
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P			B+M; B+PWD;	Note 1
Cardiac	Cardiac Pediatric	P	P	P			B+M; B+PWD;	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared through 510(k) K003399 and K010374.

Prescription Use (Per 21 CFR 801.109)

David A. Legassa

(Division Sign-Off)
Division of Reproductive, **Abdominal,**
and Radiological Devices
510(k) Number K052109